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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,982	03/11/2004	Ganapati R. Mauze	10010186-3	6847

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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,982	MAUZE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. On 15 September 2004 an advisory action was inadvertently mailed to applicant. Applicant is to disregard said advisory action as it addresses claims and amendments not of this application.

2. In accordance with the Interview Summary of 09 September 2004, the subject application, with claims 22-41 currently pending, is taken up for action.

Priority

3. This application repeats a substantial portion of prior Application No. 09/848,869, filed 04 May 2001, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Oath/Declaration

4. The oath/declaration is objected to as it does not recite the claim for benefit of priority under 35 USC 120.

Specification

5. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states at page 14:

> **All patents and publications mentioned herein, both *supra* and *infra*, are hereby incorporated by reference.**

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the

> referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

6. The disclosure is objected to because of the following informalities: The specification dos not contain as an initial statement, the claim for benefit or priority.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 22-29, 31, 33-37, 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,952,172 (Meade et al.).

9. For convenience, claims 22 and 26, the only independent claims, are reproduced below.

> 22. **(New)** A method comprising:
>
> adding a metal ion to an initial complex comprising a target and a probe labeled with a transition metal ligand complex to produce an electrically conductive complex; and,
>
> applying a potential to the electrically conductive complex to produce a detectable signal.

26. **(New)** A method comprising:

maintaining a composition comprising a target and a probe labeled with a transition metal ligand complex under conditions suitable for producing target/probe complexes;

doping said composition with a metal ion to form a doped composition; and,

applying a potential to said doped composition in order to produce a detectable signal from any target/probe complexes produced.

Also produced below are the definitions for "transition metal complexes" and the term "metal ion" as found at page 5 of the disclosure.

The term "transition metal ligand complex" refers to metal ligand complexes having centralized atoms from the transition metals of the periodic table. Transition metals include and are not limited to ruthenium, osmium, iridium etc..

The term "metal ion" refers to divalent and multivalent atoms. For example, nickel, zinc, cobalt. etc. Term also should be interpreted broadly to include elements and complexes from the lanthanide series of the periodic table. Metals have characteristic physical properties such as being efficient in conduction of heat and electricity, malleability, ductibility and a lustrous appearance. Chemically, metals lose electrons to form positive metal ions.

10. In view of the definitions, the claims have been interpreted as requiring the use of metal ions" where the atoms are not isolated, but can be part of any complex.

11. Meade et al., teach at length a method of detecting nucleic acids whereby transition metal-ligand complexes are attached to a probe that in turns hybridizes to a target nucleic acid. At column 7, an extensive list of both suitable transition metals and their ligands is provided. Column 7, fourth paragraph, teaches that nickel, zinc, cobalt (claim 25), as well as ruthenium, osmium, and iridium can be used. Column 7, lines 52-53, teach that ruthenium and osmium are

particularly preferred (limitations of claims 24, 28, and 36). At column 8, bridging to column 9, Meade et al., discloses use of an electrode or electrical potential so to cause the transition metal-ligand complex to emit light that is in turn detected.

12. While Meade et al., refers to "transition metal complexes,"

13. Meade et al., column 9, lines 45-54, teach providing metal and applicant uses the term "metal ions," such is not considered to constitute a patentable difference for as seen above, applicant stresses in their disclosure that the term "metal ions" is to be interpreted broadly, such that it encompasses complexes. Accordingly, the complexes of Meade et al., fairly anticipate the limitation of applicant's "metal ions."

14. Meade et al., column 10, bridging to column 11, teaches immobilization
Of nucleic acid probes to the surface of various solid supports. Such meets a limitation of claims 30, 32, 38, and 40.

15. For the above reasons, and in the absence of convincing evidence to he contrary, claims 22-29, 31, 33-37, 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,952,172 (Meade et al.).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 31, 33, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,952,172 (Meade et al.) in view of US Patent 6,027,889 (Barany et al.).

20. See above for the basis of the rejection as it relates to the disclosure of Made et al.

21. While Meade et al., teach explicitly of coupling of probes to a solid support, they do not teach arranging the probes in an array.

22. Barany et al., Figure 1, depicts an addressable array of probes and captured target molecules.

23. In view of the detailed teachings of Meade et al., and Barany et a., one would have been motivated to have arranged the probes in an addressable array as such is an obvious design choice recognized and used in related art at time of filing.

24. For the above reasons, and in absence of convincing evidence to contrary, claims 31, 33, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,952,172 (Meade et al.) in view of US Patent 6,027,889 (Barany et al.).

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,985,568 (Krihak et al.) disclose arrays of addressable electrodes that have probes bound thereto, which can be used in conjunction with nucleic acid hybridization reactions.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
15/09/2004